

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Art Unit: 4161

HENGYUAN Lang,

Examiner: WILLIS, Douglas M.

APPLICATION NO: 10/565,452

FILED: 5 May 2006

FOR: P-38 Kinase Inhibitors

**MS: General**

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

**PETITION REGARDING PATENT TERM ADJUSTMENT UNDER C.F.R. §1.705(b)**

Sir:

In accordance with 37 C.F.R. § 1.705(b), Applicant hereby applies for patent term adjustment under 35 U.S.C. § 154(b) of 646 days. This application is being filed within two months of the date the patent issued, as required by 37 C.F.R. § 1.705 (d).

**I. Fee**

As required by 37 C.F.R. § 1.705(b)(1), this application is accompanied by a request to charge Deposit Account No. **50-4409** for \$ 200.00 to cover the required fee (as defined in 37 C.F.R. § 1.18(e)). Please charge any deficiencies or any additional fees due in response to this request to Deposit Account **50-4409**.

**II. Statement of the Facts Involved**

**A. Correct Patent Term Adjustment**

The Issue Notification, which was mailed on June 23, 2010, indicated a Patent Term Adjustment of 746 days.

Patentee has calculated an initial patent term adjustment of 646 days based on the following facts:

### **Case Law**

In *Wyeth v. Kappos*, 2010 U.S. App. Lexis 300, the Federal Circuit affirmed the interpretation of 35 U.S.C. § 154(b)(2) by the District Court of the District of Columbia in *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 2008. The Federal Circuit affirmed the determination that the USPTO misconstrued the first sentence of 35 U.S.C. § 154(b)(2)(A), and as a result, improperly denied Wyeth a portion of patent term to which Wyeth was entitled under 35 U.S.C. § 154.

In the opinion, the Court stated that "the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for 'A delay' or for 'B delay,' whichever is larger, but never A + B." However, Plaintiff Wyeth argued that the § 154(b)(1)(A) and § 154(b)(1)(B) period overlap only if they occur on the same calendar day or days. The Court determined that Wyeth's construction of § 154(b)(2)(B) was correct.

Simply put, the holding of the Court is that the excluded overlap recited in the first sentence of 35 U.S.C. § 154(b)(2)(A) only occurs if a 35 U.S.C. § 154(b)(2)(A) period and a 35 U.S.C. § 154(b)(2)(B) period run concurrently. As such, a patent holder is entitled to recoup the 35 U.S.C. § 154(b)(2)(A) period that falls outside of the 35 U.S.C. § 154(b)(2)(B) period in addition to the 35 U.S.C. § 154(b)(2)(B) period itself.

### **Relevant Dates**

The above identified application has a 35 U.S.C. §371 filing date of May 5, 2006.

The first Office Action, which was a Restriction Requirement, was mailed on May 16, 2008, resulting in a PTO delay of 316 days beyond the 14 months provided by 35 U.S.C. §154(b).

A Response by Patentee was filed November 17, 2008, resulting in applicant delay of 93 days beyond the 3 months provided by 35 U.S.C. §154(b).

A non-final office action was mailed December 5, 2008, within the 4 months provided by 35 U.S.C. §154(b).

A Response by Patentee was filed March 5, 2009, within the 3 months provided by 35 U.S.C. §154(b).

A Final office action was mailed April 14, 2009, within the 4 months provided by 35 U.S.C. §154(b).

A Response by Patentee was filed July 13, 2009, within the 3 months provided by 35 U.S.C. §154(b).

A non-final office action was mailed July 29, 2009, within the 4 months provided by 35 U.S.C. §154(b).

A Response by Patentee was filed October 15, 2009, within the 3 months provided by 35 U.S.C. §154(b).

A Final office action was mailed December 18, 2009, within the 4 months provided by 35 U.S.C. §154(b).

A Response by Patentee was filed February 5, 2010, within the 3 months provided by 35 U.S.C. §154(b).

A notice of allowance was mailed March 8, 2010, within the 4 months provided by 35 U.S.C. §154(b).

Patentee filed an amendment under §1.312 on May 28, 2010, after the notice of allowance had been mailed. A response to the amendment under § 1.312 was mailed on June 7, 2010 resulting in a reduction of period of adjustment of patent term of 11 days as provided by 1.704(c)(10).

The issue fee has been paid on May 28, 2010, within the 3 months provided by 35 U.S.C. §154(b).

The patent will issue July 13, 2010, within the 4 months provided by 35 U.S.C. §154(b).

Accordingly, the initial PTO adjustment based on delay under 35 U.S.C. § 154(b)(2)(A) is 316 days.

The initial 35 U.S.C. § 154(b)(2)(B) period for the instant application began on May 5, 2009 (three years after the filing date of May 5, 2006) and will end on July 13, 2010 with the issuance of the instant application. The 35 U.S.C. § 154(b)(2)(B) period is 434 days

There was 0 days of PTO delay under 35 U.S.C. § 154(b)(2)(A) that occurred within the initial 35 U.S.C. § 154(b)(2)(B) period that should be excluded from the patent term adjustment calculation under the holding of *Wyeth v. Dudas*.

There were 104 days of Applicant delay under 35 U.S.C. § 154(b)(2)(C).

Accordingly, the sum of the 35 U.S.C. § 154(b)(2)(B) delay (434 days) and 35 U.S.C. § 154(b)(2)(A) delay (316 days) less the overlap days (0 days) and less Applicant delay days (104 days) results in a PTA of 646 days.

The PTA printed on the Issue Notification is 746 days. Applicants therefore respectfully request reconsideration of the PTA calculation.

**B. Terminal Disclaimer**

The above-identified patent is not subject to a Terminal Disclaimer.

**C. Reasonable Efforts**

Any applicant delays under 37 C.F.R. § 1.704 are set forth above. There were no other circumstances constituting a failure to engage in reasonable efforts to conclude processing of examination of the above-identified application, as set forth in 37 C.F.R. § 1.704.

Respectfully submitted,

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Date: June 30, 2010